

REMARKS

I. Status of the Claims

Claims 1-5 and 7-18 are pending in the application, are under examination, and stand rejected, variously, under 35 U.S.C. §112, first and second paragraphs, 35 U.S.C. §102, 35 U.S.C. §103, and for alleged double-patenting. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-18 are rejected as indefinite. Applicants traverse, and provide the following in response to each rejection.

Claims 1 and 4. Claims 1 and 4 are rejected on the grounds that "p12-similar" is not defined in the specification. Applicants traverse.

The specification on p. 8, l. 15-19 (numbering according to English version of PCT application: PCT/DE 03/02096), provides support for the bacteriophage tail proteins generally, and particular tail proteins to be used are provided at p. 11, l. 16-21. Specifically contemplated bacteriophage tail proteins are those which bind to highly conserved regions of endotoxin, in particular "p12 and p12-similar bacteriophage tail proteins," as defined at p. 11, l. 26-29.

It was known before the priority date of the present application that bacteriophage short tail fibers, especially the ones similar to p12, are often involved in host cell recognition and were suggested to bind to parts of the lipopolysaccharides on the bacterial surface (compare Riede, 1987, Mol. Gen. Genet., **206**, 110-115, and Burda & Miller, 1999, Eur. J. Biochem., **265**, 771-778). In Riede, the p12 proteins of the phages T2, K3 and K3hx were cloned and characterized. Burda & Miller discussed the role of short tail fibers (p12 proteins or gp12) in bacteriophage

infection and their binding to LPS core, including older references cited herein. In addition to T4p12, which is described in detail in the application, the short tail fibers of phage T2 and phage AR1 were in the public database before the instant priority date (see table below), and both exhibit more than 60% identity to T4p12. A BLAST search of the T4p12 sequence gives another 10 p12-like short tail fiber proteins which exhibit more than 30% identity to T4p12 protein (see table below). Hence, T4p12 can be regarded as a representative of the “p12 like protein” species of bacteriophage tail proteins suitable for use according to the present invention.

P12 like proteins in the database before the priority date (24.6.2002 & 24.2.2003)			
<u>P12 like protein</u>	<u>Amino acid identity</u>	<u>Database accession number</u>	<u>Submission date</u>
T2 gp12	93 % identity	CAA39905	07 Feb 1991
AR1 short tail fiber	63 % identity	AAN03609	04 Aug 2001

P12 like proteins in the data base after priority date(s)			
<u>P12 like protein</u>	<u>Amino acid identity</u>	<u>Database accession number</u>	<u>Submission date</u>
RB32 short tail fiber	62 % identity	YP_803101	21 Oct 2006
RB69 short tail fiber	61 % identity	AAP76072	20 May 2003
PP01 short tail fiber	61 % identity	BAD20635	21 May 2004
JS98 T4 gp12-like short tail fiber	46 % identity	AAU29286	10 Sep 2004
44RR2.8t gp12 short tail fiber	41 % identity	AAQ81466	26 Aug 2003
Aeromonas phage 31 gp12	41 % identity	AAX63634	14 Mar 2005
Phage 25 gp12 short tail fiber	40 % identity	ABF72697	04 May 2006
Phi1 gp12 short tail fiber	39 % identity	ABR24657	14 Feb 2007
RB43 short tail fiber	39 % identity	AAX78734	18 May 2005
Aehl gp12 short tail fiber	34 % identity	AAQ17871	11 Jul 2003

In support of this view, applicants provide the attached declaration of Dr. Stefan Miller, one of the inventors for the above-captioned application and president of Profos, the assignee of the above-captioned application. In his declaration, Dr. Miller explains, as set forth above, there is a

general understanding in the field that “p12-similar” would be understood as a tail fiber that binds to highly conserved regions of endotoxin and exhibit substantial sequence homology to T4p12.

The test under §112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. An examiner should allow claims which define the patentable subject matter with a *reasonable* degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of (a) the content of the particular application disclosure; (b) the teachings of the prior art; and (c) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with §112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by the statute, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) (“The requirement to ‘distinctly’ claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct

principles....Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.”).

Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term “surrender value protected investment credits” which was not defined or used in the specification was discernible and hence not indefinite because “the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence.”).

In sum, the term “p12-similar” provides sufficient notice to those of skill in the art as to the scope of the claims. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Claim 15. The claim is said to lack antecedent basis for “fluorescent-marked endotoxin.” Applicants traverse and the claim refers to this element neither as “the” or “said” endotoxin. As such the rejection is improper. However, in the interest of advancing the prosecution, an amendment has been provided that is believed to address the examiner’s concern.

Reconsideration and withdrawal of each of the foregoing rejections is respectfully requested.

III. Rejections Under 35 U.S.C. §102

A. *Suzuki et al.*

Claims 1-3, 11 and 15 are rejected as anticipated by *Suzuki et al.* Applicants again traverse. The examiner has acknowledged that the reference fails to teach the inclusion of

bivalent cations. Accordingly, claim 1 has been amended to recite this element, thereby obviating the rejection. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Baxa *et al.*

Claims 1-3 and 15 are rejected as anticipated by Baxa *et al.* Applicants again traverse. The examiner has acknowledged that the reference fails to teach the inclusion of bivalent cations. Accordingly, claim 1 has been amended to recite this element, thereby obviating the rejection. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

IV. Double-Patenting

The examiner has maintained the provisional, non-statutory double-patenting rejection over the '415 application. Because the first allowed case should be passed to issue prior to any rejections being maintained, applicants thus need not address those rejections until at least one of the two applications is allowed.

V. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at 512-536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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